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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/011,977	06/15/98	AMMON	H 015200-054

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EXAMINER

OWENS JR, H

ART UNIT

PAPER NUMBER

1623

DATE MAILED:

04/18/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/011,977

Applicant(s)
Ammon et al.

Examiner
Howard Owens

Art Unit
1623



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jun 28, 2000
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10, 12-22, 24, and 25 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10, 12-22, 24, and 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☒ Interview Summary (PTO-413) Paper No(s). 17
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) ☐ Other:

Response to Arguments

5 The following is in response to the amendment filed 6/28/00:

The finality of the rejection of the last office action is withdrawn in lieu of the citation of new art.

10 An action on the merits of claims 10, 12-22, 24 and 25 is contained herein below.

Claims 23 and 26 have been canceled by applicant.

35 U.S.C. 112

15 112(1)

The rejection of claims 10 and 12-16 under 35 U.S.C. 112(1) has been overcome through applicant's amendment.

112(2)

20 The rejection of claims 10 and 12-16 and newly added claims 17-22 and 24-25 under 35 U.S.C. 112(2) is maintained for the reasons of record, cited in the office action mailed 9/29/99.

25 In the absence of a process for the preparation of plant material and given the variety of methods available for processing plant material as well, applicant should particularly point out and distinctly claim what is intended by the terms plant extract.

Claims 22 and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claims 22 and 25 are seen as vague and indefinite for use of the terms pharmaceutical compound and pharmaceutical extract. In the absence of a chemical core or structure these terms are seen as vague within the context of the instant invention. There are a variety of compounds natural and synthetic which are considered "pharmaceutical compounds or extracts", thus applicant is required to specifically point out and distinctly the compound or extract intended, unless applicant intends to include "pharmaceutically acceptable carriers".

35 U.S.C. 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10, 12-22 and 24-25 are rejected under 35 U.S.C. over Ammon et al., EP 0552657 in combination with Mulshine et al., WO 95/24894 and Han, Chin. Med. Sci. J., vol. 9(1), 61-69.

The instant claims are drawn to a method of combating diseases selected from the group consisting of chronic bronchitis, glomerulonephritis, rheumatoid arthritis, cystic fibrosis, tumors and neoplasms or tumor metastases which are caused by increased leukocytic elastase or plasmin activity.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

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3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5 Ammon et al. teach the use of Boswellic acids for the prophylaxis and or control of inflammatory processes that are caused by elevated leucotriene formation and that they inhibit the 5-lipoxygenases. Ammon et al. teach the use of Boswellic acid in the treatment of inflammatory conditions of the joints (rheumatism), bronchitis, chronic hepatitis and chronic asthma (pp. 1-6). However, Ammon does not teach the use of Boswellic acid as an anti-tumor or anticancer agent. Mulshine et al. teaches the efficacy of 5-lipoxygenase inhibitors in the treatment of cancer, which adequately bridges the nexus between the differences in the prior art and the invention as claimed with regard to the use of Boswellic acids to treat tumors; moreover, Han further supports the usefulness of Boswellic acid derivatives in the treatment of cancer (see abstract).

15 It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to use Boswellic acid or a derivative thereof to treat inflammatory processes or neoplasms.

20 One of skill in the art would have been motivated to use Boswellic acid or plant extracts containing Boswellic acid to treat inflammation or neoplasms as the prior art teaches the anti-inflammatory and anticancer activity associated with the use of these compounds. Applicant's connection of Boswellic acid to leukocytic elastase or plasmin activity is considered to be a discovery of one of the pathways affected by Boswellic acid and does not obviate the use of the Boswellic acid in the prior art to treat or combat inflammatory conditions, neoplasms or cancer; moreover, as the prior art has taught the efficacy of 5 lipoxygenase inhibitors in the treatment of cancer or tumors and Boswellic acid has been established in the art as a member of the class of lipoxigenase inhibitors one of skill in the art would have been provided with a reasonable expectation of success in the use of these compounds to treat cancer.

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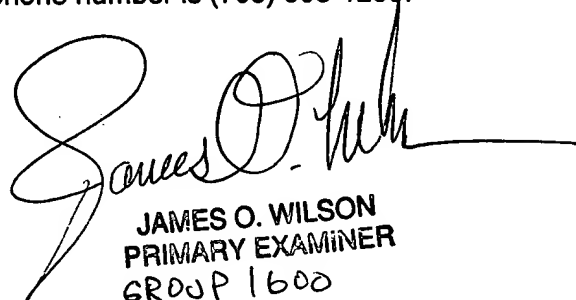
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Howard Owens whose telephone number is (703) 306-4538 . The examiner can normally be reached on Mon.-Fri. from 8:30 a.m. to 5 p.m.

5 If attempts to reach the examiner by telephone are unsuccessful, the Primary Examiner signing this action, James O. Wilson can be reached on (703) 308-4624 . The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

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JAMES O. WILSON
PRIMARY EXAMINER
GROUP 1600